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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,915	01/26/2004	Jose Vicente Murillo Garrido	9256-20US(003/PCT/02-V)	3364
570	7590	09/10/2009	EXAMINER	
PANITCH SCHWARZE BELISARIO & NADEL LLP ONE COMMERCE SQUARE 2005 MARKET STREET, SUITE 2200 PHILADELPHIA, PA 19103				QAZI, SABIHA NAIM
ART UNIT		PAPER NUMBER		
		1612		
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			09/10/2009	
			ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomail@panitchlaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/764,915	MURILLO GARRIDO ET AL.	
	Examiner	Art Unit	
	Sabiha Qazi	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 03 June 2009.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 15-34 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-14 and 35-38 (in part) is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 15-34 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/3/09</u> . | 6) <input type="checkbox"/> Other: _____ . |

Non-Final Office Action

Claims 1-38 are pending. No claim is allowed at this time.

Summary of this Office Action dated August 27, 2009

1. Information Disclosure Statement
2. Copending Applications
3. Specification
4. 35 USC § 112 Scope of Enablement Rejection
5. 35 USC § 112 (2) Rejection
6. 35 USC § 103 (a) Rejection
7. Response to Remarks
8. Communication

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

35 USC § 112 --- First Paragraph Scope oF Enablement Rejection

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 and 35-38 (in-part) rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compounds containing epoxide C-ring (as exemplified and elected), does not reasonably provide enablement for the preparation of thousands of compounds which are drawn to various structurally and chemically different compounds and process of making them as has been claimed.

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The specification does not disclose how to make all the claimed compounds. There is no guidance and/or description of the large number of compounds to prepare and use them.

2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by “undue experimentation,” the Federal Circuit has stated:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely a routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).¹

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,

¹ As pointed out by the court in In re Angstadt, 537 F.2d 498 at 504 (CCPA 1976), the key word is “undue”, not “experimentation”.

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- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

The nature of the invention

The invention relates to compounds and the processes of making the steroidal compounds with large number of substituents and the intermediates.

The level of predictability in the art: There is no guidance in the specification how to make and use the invention of the compounds of formula (1). The synthesis of such a large variety of compounds having different structures and so different chemical properties cannot be predicted. **Even when similar starting materials are used under the same conditions the products obtained are different.**

As stated in the preface to a recent treatise:

"Most non-chemists would probably be horrified if they were to learn how many attempted syntheses fail, and how inefficient research chemists are. The ratio of successful to unsuccessful chemical experiments in a normal research laboratory is far below unity, and synthetic research chemists, in the same way as most scientists, spend most of their time working out what went wrong, and why. Despite the many pitfalls lurking in organic synthesis, most organic chemistry textbooks and research articles do give the impression that organic reactions just proceed smoothly and that the total synthesis of complex natural products, for instance, is maybe a labor-intensive but otherwise undemanding task. In fact, most syntheses of structurally complex natural products are the result of several years of hard work by a team of chemists, with almost every step requiring careful optimization. The final synthesis usually looks quite different from that originally planned, because of unexpected difficulties encountered in the initially chosen synthetic sequence. Only the seasoned practitioner who has experienced for himself the many failures and frustrations which the development (sometimes even the repetition) of a synthesis usually implies will be able to appraise such work..... Chemists tend not to publish negative results, because these are, as opposed to positive results, never definite (and far too copious)". Dorwald F. A. Side Reactions in Organic Synthesis, 2005, Wiley: VCH, Weinheim pg. IX of Preface (892-reference enclosed).

Thus synthesis of the compounds of formula I containing heterocyclic or non heterocyclic groups is unpredictable for the reasons cited above..

The amount of direction or guidance provided and the presence or absence of working examples

The inventor provides very little direction in the instant specification. Only limited substituents on the compounds are made and disclosed. There is no preparation of compounds of formula (1) when wide range of compounds containing various C and D rings are prepared. The availability of the starting material that is needed to prepare the invention as claimed is also at issue here. As per MPEP 2164.01 (b): A key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to make the invention are available. The Court in In re Ghiron, 442 F.2d 985,991,169 USPQ 723,727 (CCPA 1971), made clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a chemical process. In re Howarth, 654 F.2d 103, 105,210 USPQ 689, 691 (CCPA 1981).

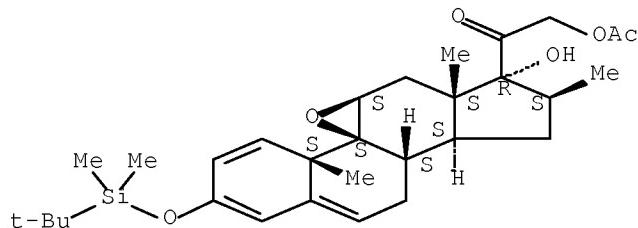
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The specification provides no direction or guidance for practicing the claimed invention in its "full scope". No reasonable specific guidance is provided. The instant specification does not have any working examples with respect to the various substituents as given above. The state of the art indicates that even when the reactants are similar, and the reaction conditions are the same, it is not necessary that it would form the same products.

The specification discloses the preparation of epoxy compounds such as cited below.

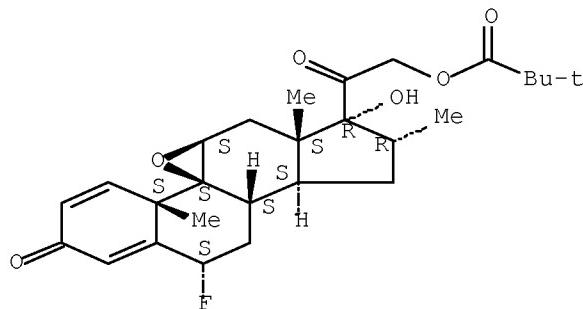
RN 494870-05-2 ZCPLUS
CN Pregna-1,3,5-trien-20-one, 21-(acetyloxy)-3-[(1,1-dimethylethyl)dimethylsilyl]oxy]-9,11-epoxy-17-hydroxy-16-methyl-, (9 β ,11 β ,16 β)- (9CI) (CA INDEX NAME)

Absolute stereochemistry.



RN 2135-16-2 ZCPLUS
CN Pregna-1,4-diene-3,20-dione, 21-(2,2-dimethyl-1-oxopropoxy)-9,11-epoxy-6-fluoro-17-hydroxy-16-methyl-, (6 α ,9 β ,11 β ,16 α)- (9CI) (CA INDEX NAME)

Absolute stereochemistry.



The amount of direction provided by the inventor

The inventor provides very little direction in the instant specification. Only limited substituents on the compounds are prepared and disclosed. **There are no compounds other than C ring as epoxy ring.** The availability of the starting material that is needed to prepare the invention as claimed is also at issue here. As per MPEP 2164.01 (b): A key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to make the invention are available. In the biotechnical area, this is often true when the product or process requires a particular strain of microorganism and when the microorganism is available only after extensive screening. The Court in *In re Ghiron*, 442 F.2d 985, 991, 169 USPQ 723,727 (CCPA 1971), made clear that if the practice of a method requires a particular apparatus, the application must provide a sufficient disclosure of the apparatus if the apparatus is not readily available. The same can be said if certain chemicals are required to make a compound or practice a chemical process. *In re Howarth*, 654 F.2d 103, 105,210 USPQ 689, 691 (CCPA 1981). There are no starting materials provided with respect to the various substituents.

The quantity of experimentation necessary

Because of the known unpredictability of the art, and in the absence of experimental evidence one skilled in the art would not be able to make and use the invention. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the claimed invention in its “full scope” a person of ordinary skill in the art would have to engage in undue experimentation, with no assurance of success.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-14 and 35-38 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply:

5. It is unclear what is the meaning of the “general formula” in claims?. It is suggested to delete this term.

6. In claim 1 in formula (VI) R can be “C1-C6 alkyl radical”. It is unclear what is intended by “radical”.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the

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subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-14 and 35-38 rejected under 35 U.S.C. 103(a) as being unpatentable over GODARD et al. (EP 610, 138), TAYLOR et al. (Tetrahedron, 55 (1999), 12431-12477), REYDELLET-CASEY et al. ((Organic Process and Research, 1997, 1, 217-221).

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TAYLOR teaches electrophilic fluorinating agents. See the entire document especially 2.1 where N-F reagents are described. It teaches the fluorinating agents as in present claims. See page compound 2 (NFSI) on 12433, compound 42 on page 12440, preparation 6-alpha fluoro steroid in scheme 35 on page 12453 and scheme 36 on page 12454.

GODARD teaches process of preparing 6-fluorinated steroids. See the entire document especially formula (V) on page 3 and 9. The compound of formula (IV) is fluorinated at 6-position. See also examples and claims.

REYDELLET-CASEY teaches agents to introduce fluorine at 6-position of the steroid skeleton. The reference discloses N-fluorobenzenesulfonimide (NFSI) of formula 4 on page 217. Same N-fluorobenzenesulfonimide has been claimed in present claimed process (see formula (V) in claim 1. See the entire document especially second column of experimental section on page 220, where general fluorination procedure using N-fluorobenzenesulfonimide (NFSI) is described.

Present claims are generically taught by the prior art cited above.

Instant claims differ from the reference in that they are of different generic scope. It had been held by Courts that the indiscriminate selection of "some" from among "many" is considered *prima facie* obvious. In re Lemin, 141 USPQ 814 (1964); National Distillers and Chem. Corp. V. Brenner, 156 USPQ 163.

The instant claimed compounds would have been obvious because one skilled in the art would have been motivated to prepare compounds embraced by the genus of

the above cited references with the expectation of obtaining additional beneficial compounds. The instant claimed process would have been suggested to one skilled in the art.

It would have been obvious to one skilled in the art to prepare 6-alpha fluoro steroids at the time the invention was filed because GODARD, TAYLOR, REYDELLET-CASEY teaches the fluorination with N-fluorobenzenesulfonimide and other reagents as has been used in present claims. One skilled in the would know how to select fluorinating reagent to prepare stereo selective 6-alpha fluoro steroids because prior art available at the time the invention was filed.

One having ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render *prima facie* obvious a species falling within the genus. In re Susi, 440 F.2d 442, 445, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in Merck & Co. V. Biocraft Laboratories, 874 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

It has been decided by the courts that “when a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious”. KSR v. Teleflex, 127 S.Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious”, the relevant question is “whether the

improvement is more than the predictable use of prior art elements according to their established functions." (*Id.*). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is... a person of ordinary creativity, not an automaton." *Id.* at 1742.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

Response to Remarks

Examiner disagrees with the arguments that all the claimed invention is related to one another and should be examined. Applicant's arguments regarding restriction requirement has been fully considered but was not found persuasive. The search for intermediate compounds as claimed is not the same as the process of making the compounds. It will be burden on the examiner to search all the different inventions for the reason cited in the previous office action. Applicant's arguments are mainly based

upon assuming that this is national stage application. This application is not a 371 application. Therefore the argument about the common property is not relevant. The restriction requirement was done based on groups. This was not the election of species. Species election was requested from the elected group to start the search and was not limited to species.

Restriction is now made final.

For Applicant's convenience invention is discussed in detail here.

Claims 1-14 are drawn to process of making the compounds of formula (I)

Claims 15-24 are drawn to compounds of formula (IV)

Claims 25-34 are drawn to process of making the compounds of formula (IV).

Claims 35-38 are drawn to compounds of formula (I).

Each compound contains different C and D rings which makes more complicated for the search. It would be great burden on the Examiner to search several patentable inventions in one application as has been clearly said in the election/restriction requirement.

Applicant's elected group VII claims 1-14 and 35-38 wherein C ring represents the second structure (epoxide) with traverse. The elected species is not a single compound therefore it is unclear what applicants mean by OP' and R4 at 16 and 17-positions. This is not the species. This includes hundreds of compounds.

The examiner has required restriction between product and process claims Groups I to IV (Product, compounds) and V (process of making). Where applicant elects claims

directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

1. Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above

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and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph. The examiner has required restriction between product and process claims Groups I to IV (Product, compounds) and V (process of making). Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process

claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

In order to advance the prosecution Applicant may consider calling the Examiner to discuss the issues surrounding this application.

Communication

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day except Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Krass Frederick can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sabiha Qazi/
Primary Examiner, Art Unit 1612